

What is Claimed:

1. A method of providing neuroprotection to the central or peripheral nervous system of a subject in need of such neuroprotection comprising periodically administering to the subject an amount of glatiramer acetate and an amount of 2-amino-6-trifluoromethoxybenzathiazole, wherein the amounts when taken together are effective to provide neuroprotection to the central or peripheral nervous system of the subject.
2. The method of claim 1, wherein providing neuroprotection comprises treating a neurodegenerative disease.
3. The method of claim 2, wherein the neurodegenerative disease is multiple sclerosis, amyotrophic lateral sclerosis, acute disseminated encephalomyelitis, adrenleukodystrophy, adrenomyeloneuropathy, Leber's hereditary optic atrophy, Human Lymphotropic T-cell Virus I (HTLV I)-associated myelopathy, acute viral encephalitis, aseptic meningitis, virus-induced demyelination, demyelinating genetic diseases, transverse myelitis, Progressive Multifocal Leukoencephalopathy, a nutritional metabolic disorder, acute glaucoma, chronic glaucoma, close-angle glaucoma, open-angle glaucoma, optic neuritis or systemic lupus erythematosus.
4. The method of claim 3, wherein the neurodegenerative disease is multiple sclerosis.
5. The method of claim 3, wherein the neurodegenerative disease is amyotrophic lateral sclerosis.
6. The method of claim 3, wherein the neurodegenerative disease is acute close-angle glaucoma.

-65-

7. The method of claim 3, wherein the neurodegenerative disease is optic neuritis.
- 5 8. The method of claim 3, wherein the neurodegenerative disease is systemic lupus erythematosus.
9. The method of claim 1, wherein providing neuroprotection comprises treating neurotrauma.
- 10 10. The method of claim 9, wherein the neurotrauma is a result of a traumatic event selected from the group consisting of head trauma, spinal trauma, neurotoxic injury, eye injury, stroke, ischemia, hypoxia, and anoxia.
- 15 11. The method of claim 10, wherein the neurotrauma is a result of eye injury.
12. The method of claim 1, wherein providing neuroprotection comprises providing protection against toxic levels of glutamate.
- 20 13. The method of claim 1, wherein providing neuroprotection comprises providing protection against toxic levels of monoamine oxidase-B activity.
- 25 14. The method of claim 1, wherein the subject is a human being.
15. The method of claim 1, wherein each of the amount of glatiramer acetate when taken alone, and the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone is effective to provide neuroprotection to the central or peripheral nervous system of the subject.
- 30 16. The method of claim 1, wherein either the amount of

-66-

5 glatiramer acetate when taken alone, the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone or each such amount when taken alone is not effective to provide neuroprotection to the central or peripheral nervous system of the subject.

17. The method of claim 1, wherein the amount of glatiramer acetate is in the range from 10 to 600 mg/week.

10 18. The method of claim 17, wherein the amount of glatiramer acetate is 300 mg/week.

19. The method of claim 1, wherein the amount of glatiramer acetate is in the range from 50 to 150 mg/day.

15 20. The method of claim 19, wherein the amount of glatiramer acetate is 100 mg/day.

20 21. The method of claim 1, wherein the amount of glatiramer acetate is in the range from 10 to 80 mg/day.

22. The method of claim 21, wherein the amount of glatiramer acetate is 20 mg/day.

25 23. The method of claim 1, wherein the periodic administration of glatiramer acetate is effected daily.

24. The method of claim 1, wherein the periodic administration of glatiramer acetate is effected twice daily at one half the
30 amount.

25. The method of claim 1, wherein the periodic administration of glatiramer acetate is effected once every 5 to 9 days.

35 26. The method of claim 1, wherein the periodic administration

-67-

of 2-amino-6-trifluoromethoxybenzathiazole is effected at least one hours before or at least two hours after a meal.

5 27. The method of claim 1, wherein the administration of the glatiramer acetate substantially precedes the administration of the 2-amino-6-trifluoromethoxybenzathiazole.

10 28. The method of claim 1, wherein the administration of the 2-amino-6-trifluoromethoxybenzathiazole substantially precedes the administration of the glatiramer acetate.

29. The method of claim 1, wherein the administration of the glatiramer acetate is effected subcutaneously, intraperitoneally, intravenously, intramuscularly, intraocularly
15 or orally and the administration of the 2-amino-6-trifluoromethoxybenzathiazole is effected orally.

30. The method of claim 29, wherein the administration of the glatiramer acetate is effected subcutaneously and the
20 administration of the 2-amino-6-trifluoromethoxybenzathiazole is effected orally.

31. A package comprising

- 25 i) a first pharmaceutical composition comprising an amount of glatiramer acetate and a pharmaceutically acceptable carrier;
- ii) a second pharmaceutical composition comprising an amount of 2-amino-6-trifluoromethoxybenzothiazole and a pharmaceutically acceptable carrier; and
- 30 iii) instructions for use of the first and second pharmaceutical compositions together to provide neuroprotection to the central or peripheral nervous system of a subject in need of such neuroprotection.

35 32. The package of claim 31, wherein the amount of glatiramer

-68-

acetate is 300 mg.

33. The package of claim 31, wherein the amount of glatiramer acetate is 20 mg.

5

34. The package of claim 31, wherein providing neuroprotection comprises treating a neurodegenerative disease.

10

35. The package of claim 34, wherein the neurodegenerative disease is multiple sclerosis, amyotrophic lateral sclerosis, acute disseminated encephalomyelitis, adrenleukodystrophy, adreno-myeloneuropathy, Leber's hereditary optic atrophy, Human Lymphotropic T-cell Virus I (HTLV-I)-associated myelopathy, acute viral encephalitis, aseptic meningitis, virus-induced demyelination, demyelinating genetic diseases, transverse myelitis, Progressive Multifocal Leukoencephalopathy, a nutritional metabolic disorder, acute glaucoma, chronic glaucoma, close-angle glaucoma, open-angle glaucoma, optic neuritis or systemic lupus erythematosus.

20

36. The package of claim 35, wherein the neurodegenerative disease is multiple sclerosis.

25

37. The package of claim 35, wherein the neurodegenerative disease is amyotrophic lateral sclerosis.

38. The package of claim 35, wherein the neurodegenerative disease is acute close-angle glaucoma.

30

39. The package of claim 35, wherein the neurodegenerative disease is optic neuritis.

40. The package of claim 35, wherein the neurodegenerative disease is systemic lupus erythematosus.

35

-69-

41. The package of claim 31, wherein providing neuroprotection comprises treating neurotrauma.

5 42. The package of claim 41, wherein the neurotrauma is a result of a traumatic event selected from the group consisting of head trauma, spinal trauma, neurotoxic injury, eye injury, stroke, ischemia, hypoxia, and anoxia.

10 43. The package of claim 42, wherein the neurotrauma is a result of eye injury.

15 44. The package of claim 31, wherein providing neuroprotection comprises providing protection against toxic levels of glutamate.

45. The package of claim 31, wherein providing neuroprotection comprises providing protection against toxic levels of monoamine oxidase-B activity.

20 46. A pharmaceutical composition comprising an amount of glatiramer acetate and an amount of 2-amino-6-trifluoromethoxybenzothiazole, wherein the amounts when taken together are effective to provide neuroprotection to the central or peripheral nervous system of a subject in need of such
25 neuroprotection.

30 47. The pharmaceutical composition of claim 46, wherein each of the amount of glatiramer acetate when taken alone and the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone is effective to provide neuroprotection to the central or peripheral nervous system of the subject.

48. The pharmaceutical composition of claim 46, wherein either of the amount of glatiramer acetate when taken alone, or the

-70-

amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone or each such amount when taken alone is not effective to provide neuroprotection to the central or peripheral nervous system of the subject.

5

49. The pharmaceutical composition of claim 46, wherein providing neuroprotection comprises treating a neurodegenerative disease.

10

50. The pharmaceutical composition of claim 49, wherein the neurodegenerative disease is multiple sclerosis, amyotrophic lateral sclerosis, acute disseminated encephalomyelitis, adrenoleukodystrophy, adreno-myeloneuropathy, Leber's hereditary optic atrophy, Human Lymphotropic T-cell Virus I (HTLVI)-associated myelopathy, acute viral encephalitis, aseptic meningitis, virus-induced demyelination, demyelinating genetic diseases, transverse myelitis, Progressive Multifocal Leukoencephalopathy, a nutritional metabolic disorder, acute glaucoma, chronic glaucoma, close-angle glaucoma, open-angle

20

glaucoma, optic neuritis or systemic lupus erythematosus.

51. The pharmaceutical composition of claim 50, wherein the neurodegenerative disease is multiple sclerosis.

25

52. The pharmaceutical composition of claim 50, wherein the neurodegenerative disease is amyotrophic lateral sclerosis.

53. The pharmaceutical composition of claim 50, wherein the neurodegenerative disease is acute close-angle glaucoma.

30

54. The pharmaceutical composition of claim 50, wherein the neurodegenerative disease is optic neuritis.

55. The pharmaceutical composition of claim 50, wherein the neurodegenerative disease is systemic lupus erythematosus.

35

-71-

56. The pharmaceutical composition of claim 50, wherein providing neuroprotection comprises treating neurotrauma.

5 57. The pharmaceutical composition of claim 46, wherein the neurotrauma is a result of a traumatic event selected from the group consisting of head trauma, spinal trauma, neurotoxic injury, eye injury, stroke, ischemia, hypoxia, and anoxia.

10 57. The pharmaceutical composition of claim 57, wherein the neurotrauma is a result of eye injury.

58. The pharmaceutical composition of claim 46, wherein providing neuroprotection comprises providing protection against toxic levels of glutamate.

15 59. The pharmaceutical composition of claim 46, wherein providing neuroprotection comprises providing protection against toxic levels of monoamine oxidase-B activity.

20 60. A method of treating a subject afflicted with amyotrophic lateral sclerosis comprising periodically administering to the subject an amount of glatiramer acetate and an amount of 2-amino-6-trifluoromethoxybenzathiazole, wherein the amounts when taken together are effective to alleviate a symptom of
25 amyotrophic lateral sclerosis in the subject so as to thereby treat the subject.

61. The method of claim 60, wherein the subject is a human being.

30 62. The method of claim 60, wherein each of the amount of glatiramer acetate when taken alone, and the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone is effective to alleviate the symptom of amyotrophic lateral sclerosis.

-72-

63. The method of claim 60, wherein either the amount of
glatiramer acetate when taken alone, the amount of 2-amino-6-
trifluoromethoxybenzathiazole when taken alone or each such
amount when taken alone is not effective to alleviate the
5 symptom of amyotrophic lateral sclerosis.

64. The method of claim 60, wherein the symptom is twitching,
cramping, loss of motor control, or difficulties in speaking,
10 swallowing or breathing.

65. The method of claim 60, wherein the amount of glatiramer
acetate is in the range from 10 to 600 mg/week.

66. The method of claim 65, wherein the amount of glatiramer
15 acetate is 300 mg/week.

67. The method of claim 60, wherein the amount of glatiramer
acetate is in the range from 50 to 150 mg/day.

68. The method of claim 67, wherein the amount of glatiramer
20 acetate is 100 mg/day.

69. The method of claim 60, wherein the amount of glatiramer
acetate is in the range from 10 to 80 mg/day.

70. The method of claim 69, wherein the amount of glatiramer
25 acetate is 20 mg/day.

71. The method of claim 60, wherein the periodic administration
30 of glatiramer acetate is effected daily.

72. The method of claim 60, wherein the periodic administration
of glatiramer acetate is effected twice daily at one half the
amount.

35

-73-

73. The method of claim 60, wherein the periodic administration of glatiramer acetate is effected once every 5 to 9 days.

5 74. The method of claim 60, wherein the periodic administration of 2-amino-6-trifluoromethoxybenzathiazole is effected at least one hours before or at least two hours after a meal.

75. The method of claim 60, wherein the administration of the glatiramer acetate substantially precedes the administration of
10 the 2-amino-6-trifluoromethoxybenzathiazole.

76. The method of claim 60, wherein the administration of the 2-amino-6-trifluoromethoxybenzathiazole substantially precedes the administration of the glatiramer acetate.
15

77. The method of claim 60, wherein the administration of the glatiramer acetate is effected subcutaneously, intraperitoneally, intravenously, intramuscularly, intraocularly or orally and the administration of the 2-amino-6-trifluoromethoxybenzathiazole is effected orally.
20

78. The method of claim 77, wherein the administration of the glatiramer acetate is effected subcutaneously and the administration of the 2-amino-6-trifluoromethoxybenzathiazole is effected orally.
25

79. A package comprising

- 30 i) a first pharmaceutical composition comprising an amount of glatiramer acetate and a pharmaceutically acceptable carrier;
ii) a second pharmaceutical composition comprising an amount of 2-amino-6-trifluoromethoxybenzothiazole and a pharmaceutically acceptable carrier; and
35 iii) instructions for use of the first and second pharmaceutical compositions together to alleviate a symptom of amyotrophic lateral sclerosis in a subject.

-74-

80. The package of claim 79, wherein the amount of glatiramer acetate is 300 mg.

5 81. The package of claim 79, wherein the amount of glatiramer acetate is 20 mg.

10 82. A pharmaceutical composition comprising an amount of glatiramer acetate and an amount of 2-amino-6-trifluoromethoxybenzothiazole, wherein the amounts when taken together are effective to alleviate a symptom of amyotrophic lateral sclerosis in a subject.

15 83. The pharmaceutical composition of claim 82, wherein each of the amount of glatiramer acetate when taken alone and the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone is effective to alleviate the symptom of amyotrophic lateral sclerosis.

20 84. The pharmaceutical composition of claim 82, wherein either of the amount of glatiramer acetate when taken alone, or the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone or each such amount when taken alone is not effective to alleviate the symptom of amyotrophic lateral sclerosis.

25 85. A method of treating a subject afflicted with a form of multiple sclerosis comprising periodically administering to the subject an amount of glatiramer acetate and an amount of 2-amino-6-trifluoromethoxybenzathiazole, wherein the amounts when taken together are effective to alleviate a symptom of the form
30 of multiple sclerosis in the subject so as to thereby treat the subject.

86. The method of claim 85, wherein the form of multiple sclerosis is relapsing-remitting multiple sclerosis.

-75-

87. The method of claim 85, wherein the subject is a human being.

5 88. The method of claim 85, wherein each of the amount of glatiramer acetate when taken alone, and the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone is effective to alleviate the symptom of the form of multiple sclerosis.

10 89. The method of claim 85, wherein either the amount of glatiramer acetate when taken alone, the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone or each such amount when taken alone is not effective to alleviate the symptom of the form of multiple sclerosis.

15 90. The method of claim 85, wherein the symptom is the frequency of relapses, the frequency of clinical exacerbation, or the accumulation of physical disability.

20 91. The method of claim 85, wherein the amount of glatiramer acetate is in the range from 10 to 600 mg/week.

92. The method of claim 91, wherein the amount of glatiramer acetate is 300 mg/week.

25 93. The method of claim 85, wherein the amount of glatiramer acetate is in the range from 50 to 150 mg/day.

94. The method of claim 93, wherein the amount of glatiramer acetate is 100 mg/day.

30

95. The method of claim 85, wherein the amount of glatiramer

-76-

acetate is in the range from 10 to 80 mg/day.

96. The method of claim 95, wherein the amount of glatiramer acetate is 20 mg/day.

5

97. The method of claim 85, wherein the periodic administration of glatiramer acetate is effected daily.

10

98. The method of claim 85, wherein the periodic administration of glatiramer acetate is effected twice daily at one half the amount.

15

99. The method of claim 85, wherein the periodic administration of glatiramer acetate is effected once every 5 to 9 days.

20

100. The method of claim 85, wherein the periodic administration of 2-amino-6-trifluoromethoxybenzathiazole is effected at least one hours before or at least two hours after a meal.

25

101. The method of claim 85, wherein the administration of the glatiramer acetate substantially precedes the administration of the 2-amino-6-trifluoromethoxybenzathiazole.

102. The method of claim 85, wherein the administration of the 2-amino-6-trifluoromethoxybenzathiazole substantially precedes the administration of the glatiramer acetate.

30

103. The method of claim 85, wherein the administration of the glatiramer acetate is effected subcutaneously, intraperitoneally, intravenously, intramuscularly, intraocularly or orally and the administration of the 2-amino-6-

-77-

trifluoromethoxybenzathiazole is effected orally.

104. The method of claim 103, wherein the administration of the
glatiramer acetate is effected subcutaneously and the
5 administration of the 2-amino-6-trifluoromethoxybenzathiazole is
effected orally.

105. A package comprising

- 10 i) a first pharmaceutical composition comprising an
amount of glatiramer acetate and a pharmaceutically
acceptable carrier;
- ii) a second pharmaceutical composition comprising an
amount of 2-amino-6-trifluoromethoxybenzothiazole and
a pharmaceutically acceptable carrier; and
- 15 iii) instructions for use of the first and second
pharmaceutical compositions together to alleviate a
symptom of a form of multiple sclerosis in a subject.

106. The package of claim 105, wherein the amount of glatiramer
20 acetate is 300 mg.

107. The package of claim 105, wherein the amount of glatiramer
acetate is 20 mg.

25 108. A pharmaceutical composition comprising an amount of
glatiramer acetate and an amount of 2-amino-6-
trifluoromethoxybenzothiazole, wherein the amounts when taken
together are effective to alleviate a symptom of a form of
multiple sclerosis in a subject.

30

109. The pharmaceutical composition of claim 108, wherein each
of the amount of glatiramer acetate when taken alone and the

-78-

amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone is effective to alleviate the symptom of multiple sclerosis.

- 5 110. The pharmaceutical composition of claim 108, wherein either of the amount of glatiramer acetate when taken alone, or the amount of 2-amino-6-trifluoromethoxybenzathiazole when taken alone or each such amount when taken alone is not effective to alleviate the symptom of multiple sclerosis.